

REMARKS

Claims 1-10 are pending. Claims 3 and 4 stand withdrawn. In the Office Action dated October 7, 2009, the Examiner indicated that Claims 1, 5 and 9 are allowable and rejected claims 2, 6-8 and 10 under 35 U.S.C., 112. The Examiner further indicated that a new title is required.

By this amendment, Applicants have amended claims 1, 2, 6 and 8. No new matter has been added. Applicants respectfully request reconsideration and allowance of all pending claims in view of the amendments and remarks set forth below.

1. **PUBLIC USE OR SALE OF PRODUCT(S) COVERED BY THE CLAIMS**

The undersigned thanks Examiner Ouspenskii for consideration and courtesy extended during the personal interview of August 14, 2009. At the Interview, the undersigned counsel exhibited the packaging for the product Impaza sold in the Russian Federation. For avoidance of doubt, Applicant herewith submits evidence that the Impaza product was not in public use or on sale in this country more than one year prior to the date of the present application.

Attached herewith is a Declaration of Dr. Oleg Epshtein (“*Epshtein Declaration I*” – **Exhibit A**), the General Director (CEO) of the Materia Medica Holding. Materia Medica Holding sells Impaza in the Russian Federation. The *Epshtein Declaration I* is evidence that (a) Materia Medica Holding did not offer Impaza for sale in the United States within the relevant time period; (b) Materia Medica Holding did not cause Impaza to be used in public within the relevant time period; and (c) Materia Medica did not cause third parties to use Impaza in public within the relevant time period. While the *Epshtein Declaration I* declares the absence of use or sale before January 22, 2005, the inclusion of this date should not constitute an admission that the January 22, 2005 date is of the essence.

2. **NEW TITLE**

Applicants have amended title. As amended, the title is now clearly indicative of the invention to which the claims are directed.

3. **ALLOWED CLAIMS 1, 5 AND 9**

a. Newly Submitted Art

The examiner issued the current office action on October 7, 2009 and indicated that claims 1, 5 and 9 are allowable. On October 13, 2009, before being aware of the office action, Applicant submitted an Information Disclosure Statement, which included, *inter alia*, a translation of the publication by Borovskaya, et al., (hereinafter “the *Borovskaya article*”). The undersigned considers it necessary to bring this publication to the Examiner’s attention.

Attached herewith are (i) (**Exhibit B**) - a copy of the *Borovskaya article* in the Russian language and its English translation; (ii) (**Exhibit C**) - the first and last pages of the journal that contains the *Borovskaya article* (iii) (**Exhibit D**) - a verified translation of the last page included in Exhibit C. The translation was carried out by the undersigned who is fluent in both Russian and English. Also included in Exhibit D is the verification affidavit.

The last page of the journal includes the “signed for publication” date of September 1, 2001. While the actual date on which the document became part of the public domain may be later, Applicant will proceed as if the September 1, 2001 date is the date in which the *Borovskaya article* became available to the public. Thus, if the *Borovskaya article* is prior art, it qualifies only under 35 USC 102(a).

b. The Law Related To Scope of Prior Art

35 U.S.C. 102(a) provides that a person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent. The term “others” in 35 U.S.C. 102(a) refers to any entity which is different from the inventive entity. See *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982) (It is well established that for a reference to be available as prior art under 35 USC 102(a) that reference must be by another). The fact that an application has named a different inventive entity than the prior art, does not necessarily make that patent prior art. *Applied Materials Inc. v. Gemini Research Corp.*, 835 F.2d 279, 15 USPQ2d 1816

(Fed. Cir. 1988). When satisfactory evidence of inventorship in fact is provided, the court must look beyond the names of the inventors listed on the patents.

In *Riverwood International Corporation v. R.A. Jones & Co., Inc.*, 324 F.3d 1346 (CAFC 2003), the court examined the issue of whether different inventors listed on the cited art constituted the same inventive entity. In *Riverwood*, the prior art patent was to Ziegler, Olson and Lovold and the later patent at issue was to Ziegler, Lashyro and Vulgamore. The court (citing *In re DeBaun*, 687 F.2d 459, 462 (Cust. & Pat. App. 1982)) found that: “What is significant is not merely the differences in the listed inventors, but whether the portions of the reference relied on as prior art, and the subject matter of the claims in question, represent the work of a common inventive entity.”

In *In re Blout and Rogers*, 333 F.2d 928, 52 CCPA 751 (1964) a reference by Rogers alone, disclosing the invention of Blout-and-Rogers, was cited as prior art against the joint application of Blout-and-Rogers. Blout and Rogers filed an affidavit attributing the relevant disclosure of the Rogers patent to Blout-and-Rogers and thus showing that the invention was by Blout-and-Rogers and the prior art was by Blout and Rogers. Accordingly, the affidavit, showed that while the named “inventive entity” were not the same, the relevant part of the prior art were work of the same inventors named in the Blout-and-Rogers application. The court held that the Rogers reference was not properly a reference against Blout-and-Rogers.

In *In re Mathews*, 408 F.2d 1393, 161 U.S.P.Q. 276, 56 CCPA 1033 (1969), the prior art was a patent by Dewey which disclosed but did not claim the invention claimed by Mathews. Mathews filed an affidavit showing that the relevant part of the disclosure of Dewey was his own work. Such showing made the prior art by Mathews and the invention by Mathews. Again, there was clear showing that the same author was the source of the subject matter at issue. The court stated that the “Dewey's affidavit and Mathews' oath accompanying his application are sufficient, we feel, to prove that the relevant disclosure in Dewey was a disclosure of Mathews' invention. The Dewey disclosure relied on, being a disclosure of Mathews' own invention, does not establish lack of novelty of Mathews' claimed invention.” *In re Mathews*, 408 F.2d 1393, at 1396. See also

In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982) (Eight months before the effective filing date of the patent in question, an article co-authored by Chiorazzi, Eshhar and Katz was published. There was no dispute that the article fully described the claimed invention. Katz filed a declaration in which he declared that he was a co-author of the article and the sole inventor of the subject matter in question. The Court found that the Katz's Declaration was sufficient to show that the cited publication disclosed his invention and that he was the sole inventor of the claimed invention).

In *In re DeBaun*, 687 F.2d 459 (Cust. & Pat. App. 1982) and *Avocent Huntsville Corp. v. ClearCube Technology, Inc.*, 443 F.Supp.2d 1284, (D.C. Ala 2006) the court examined the issue of what constitutes sufficient evidence in demonstrating inventorship. In *In re DeBaun*, the examiner rejected the claims of an application to DeBaun under 35 U.S.C. §103 in view of a patent to DeBaun-and-Noll. DeBaun argued that the art cited against him (the patent to DeBaun-and-Noll) was not prior art under § 102(e) and submitted a declaration stating that he was the sole inventor of the subject matter on which the examiner's rejection relied. The Examiner maintained the rejection and concluded that the declaration was insufficient to show that DeBaun was the sole inventor. The Board sustained the rejection. The court in *DeBaun*, stated that when one of two (or more) inventors named on a patent contends that certain elements of the patent claims are his own work, he must provide satisfactory evidence showing that the reference is his own work, 687 F.2d at 463 (citing *In re Facius*, 56 CCPA 1348, 408 F.2d 1397, 1406 (Cust. & Pat. App. 1969). See also *In re Land* (an unequivocal declaration suffices, provided it is corroborated.). The court found the unequivocal declaration to be satisfactory and sufficient evidence, and in reversing the rejection, the court held that the examiner should have considered the declaration as evidence that DeBaun was the sole inventor. *Id.* at 462.

In *Avocent Huntsville Corp. v. ClearCube Technology, Inc, supra*, defendants contended that a patent issued to Asprey as the sole inventor (the sole patent) constitutes §103 prior art as to claims 1, 6 and 16-18 of the patent issued to Asprey, Kirshtein and Lusk (the joint patent). The questions was whether the inventive entities were the same or different. Avocent submitted the sworn declarations of Asprey and Kirshtein, two of the three inventors named in the joint patent

declaring that Asprey was the sole inventor of the subject matter recited in claims 1, 6 and 16-18 of the joint patent. The court stated that Asprey's statements were wholly corroborated by Kirstein's declaration who swore that he did not invent the subject matter recited in claims 1, 6 and 16-18 of the joint patent and that to his knowledge Asprey was the sole inventor of said claims.

c. The Law Establishes That The Borovskaya Article Is Not Prior Art Under §102(a)

As discussed above, the *Borovskaya article* became part of the public domain, if at all, on or after September 1, 2001. The present application was filed in the United States on January 22, 2005, and claims priority to August 2, 2002 (PCT/RU02/00368). Therefore, the *Borovskaya article* was published less than 12 months prior to the priority date of present application. Thus, if the *Borovskaya article* is prior art, it qualifies only under 35 USC 102(a).

The *Borovskaya article* was co-authored by O. I. Epshtein, T.G. Borovskaya, O. P. Loskutova and M.S. Zak. The *Borovskaya article* discloses experiments carried out using homeopathic doses of antibodies to endothelial nitric oxide synthase.

Submitted herewith is a Declaration of Dr. Oleg Epshtein (*Epshtein Declaration II – Exhibit E*) which states (paragraph 7) that the portion of the *Borovskaya article* related to the present invention was invented solely by him, without any participation of the co-authors of the publication. *Epshtein Declaration II* is sufficient to establish that he is the sole inventor of homeopathic doses of antibodies to endothelial NO synthase that was used in the experiments described in the *Borovskaya article*. See *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982) (holding that uncollaborated affidavit is sufficient to show sole inventorship). Submitted herewith is a Declaration of T.G. Borovskaya (**Exhibit F**) wholly corroborating *Epshtein Declaration II*. *Epshtein Declaration II* and the Declaration of T.G. Borovskaya are un-rebutted evidence that Dr. Oleg Epshtein was solely responsible for inventing the biologically active substance disclosed in the *Borovskaya article*.

The named co-inventors of the present patent application were Oleg Epshtein, Evgeny Goldberg, and Alexander Dygay. *Epshtein Declaration II*, states (paragraph 8) that he is the sole

inventor of the subject matter of the claims of the present application. Dr. Epshtein's statement is wholly collaborated by the Declaration of Alexander Dygay (**Exhibit G**). Thus, Dr. Epshtein has established that he was solely responsible for inventing the subject matter of the presently pending application, namely homeopathically activated (or "potentiated") form of polyclonal antibodies to nitric oxide synthase.

Therefore, Dr. Oleg Epshtein has provided satisfactory and unequivocal evidence showing that the relevant portion of the *Borovskaya article* and the subject matter of the claims as amended is Dr. Epshtein's own work. See *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982); *Riverwood International Corporation v. R.A. Jones & Co., Inc.*, 324 F.3d 1346 (CAFC 2003); *In re Blout and Rogers*, 333 F.2d 928, 52 CCPA 751 (1964); *In re Mathews*, 408 F.2d 1393, 161 U.S.P.Q. 276, 56 CCPA 1033 (1969); *In re DeBaun*, 687 F.2d 459 (Cust. & Pat. App. 1982); and *Avocent Huntsville Corp. v. ClearCube Technology, Inc.*, 443 F.Supp.2d 1284 (D.C. Ala 2006).

Applicant, therefore, submits that the *Borovskaya article* is not available as a §102(a) reference against the presently pending claims of the present application and is thus not an appropriate reference under section §102(a). Accordingly, the *Borovskaya article* is not prior art reference and the Applicant submits that claims 1, 5 and 9 continue to be allowable.

II. Inventive Entity

Based on the foregoing, it is evident that Dr. Oleg Epshtein is the sole inventor of claims 1-2 and 5-10 as now pending. Under 37 CFR §1.48(b) when claims are narrowed or changed so that former inventors are no longer properly named, the attorney must request correction of inventorship to reflect amendment of the claims. Since, neither Goldberg nor Dygay are in fact co-inventors of claims 1-2 and 5-10, Applicant submits that correction of inventorship is required under 37 CFR §1.48(b), so as to delete Alexander Mikhailovich Dygay and Evgeny D. Goldberg as inventors and identify Dr. Oleg I. Epshtein as the sole inventor of claims 1-2 and 5-10.

While Applicant does not represent that Goldberg and Dygay were properly or improperly named in the application as filed, Applicant asserts that the inventive efforts of each inventor being

deleted are clearly no longer claimed in the present nonprovisional application. Applicant further requests that the Examiner forward the application to the Office of Initial Patent Examination for issuance of a corrected filing receipt and correction of Office records to reflect the inventorship as corrected.

4. **SECTION 112 REJECTIONS**

Claims 2 and 8 are rejected under 35 U.S.C. §112, second paragraph as being indefinite in the recitation of an antibody. Applicant has amended claims 2 to indicate that the antibody is to whole NO synthase and claim 8 to indicate that the antibody is to a fragment of NO synthase. Support for amendment to claims 2 and 8 may be found in the specification at page 1, paragraph 6. On the basis of the foregoing, withdrawal of the rejection is respectfully requested.

Claims 6, 7 and 10 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written requirement in that the term “having” is interpreted as containing sequences in addition to those specifically recited. As amended, claim 6 does not contain the term “having.” Claims 7 and 10 depend from claim 6. Applicants respectfully submit that amended claims 6-7 and 10 are fully supported in the application as filed.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event that there are any fees due and owing in connection with this matter, please charge the same to our Deposit Account No. 50-4711.

Respectfully submitted,

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Dated: December 22, 2009

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